PATENT SPECIFICATION

NO DRAWINGS

835,956

Date of Application and filing Complete Specification: Sept. 17, 1957.

No. 29222/57.

Application made in United States of America on Oct. 4, 1956.

Complete Specification Published: May 25, 1960.

Index at acceptance:—Class 81(1), B6.

International Classification:—A61k.

COMPLETE SPECIFICATION

Process for Coating Tablets

ERRATA

SPECIFICATION NO. 835,956

Page 2, line 15, *after* ingredients *for* "comma" *read* "semi-colon".

Page 2, line 80, *for* "suitable" *read* "suitably".

Page 2, line 92, *after* "and" *insert* "comma".

Page 3, line 48, *after* "weighing" *insert* "about".

Page 4, Example I and Page 5, Example II } *after* "Erythrosine" *delete* "comma".

Page 4, line 38 and Page 5, line 14 } *after* "Pan" *insert* " - ".

Page 5, line 24, *for* "disintegrate" *read* "disintegrated".

THE PATENT OFFICE,
2nd December, 1960.

DS 83379/1(10)/8512 200 11/60 D1

gredients which may or may not produce some toxic manifestations in some people, others have coatings that do not sufficiently readily dissolve in the intestinal tract, others have coatings not sufficiently hard and elastic to ensure that the coating will not chip or break readily if the pill or tablet should be bitten by the individual taking it or if the pills bump against each other in the routine packaging and handling of merchandise of this type.

While gelatin has been used for coating tablet and pill cores, the only practical method previously used for its application has been to encase the cores in sheet gelatin, which requires

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with a sub-coating and sizing material, while the cores are rotating in a coating pan, an amount of an aqueous solution of gelatin and sugar containing 1.5 to 4.5 parts by weight of gelatin to 1 part by weight of sugar just sufficient to produce a thin film of the solution over the cores, then, at the moment the coated cores begin to adhere to one another, applying sufficient talc to allow the coated cores to roll free, drying the coating with cold air and repeating these steps in sequence until a coating of desired thickness is obtained. By the technique of this invention the coating can be applied in an apparatus of the type con-

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We, MERCK & CO., INC., a corporation duly organised and existing under the laws of the State of New Jersey, United States of America, of Rahway, New Jersey, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to the pan-coating of medicinal tablets or pill cores.

The problems of coating pill and tablet cores containing medicinal substances constantly confronts drug manufacturers, because most medicinal agents taste unpleasant and many of them react with the coating material in a deleterious manner with the result that after a certain time the coating and/or the core material break down and the tablet or pill becomes worthless either because of the inactivation of the therapeutic ingredients in the core or spoiling of the coating material, which give rise to products that meet consumer resistance.

Many coatings have been suggested by prior workers in this field to overcome these difficulties and disadvantages but substantially all of them suffer from one or more drawbacks. Some coatings require special equipment for their application to the core material, others require the use of unusual or expensive ingredients which may or may not produce some toxic manifestations in some people, others have coatings that do not sufficiently readily dissolve in the intestinal tract, others have coatings not sufficiently hard and elastic to ensure that the coating will not chip or break readily if the pill or tablet should be bitten by the individual taking it or if the pills bump against each other in the routine packaging and handling of merchandise of this type.

While gelatin has been used for coating tablet and pill cores, the only practical method previously used for its application has been to encase the cores in sheet gelatin, which requires special apparatus. Clarkson, in his book entitled "Tablet Coating" Published by Drug & Cosmetic Industry, Copyright 1951, Drug Markets Inc., New York 1, N.Y., described pan-coating cores with a gelatin-acacia mixture, but while two or three layers of this solution can be applied to cores, it is not feasible to apply the multiple layers needed to make a durable, hard and pharmaceutically elegant and commercially acceptable coating. A coating comprising a mixture of gelatin and acacia remains permanently tacky, and since the viscosity decreases as the temperature increases, the coated tablets and pills stick together forming unusable agglomerates.

In accordance with the present invention, there are provided medicinal tablets or pills including a core comprising a medicament and an exterior coating comprising a multiplicity of thin, superimposed layers of intermixed gelatin and sugar in the proportion of 1.5 to 4.5 parts by weight of gelatin to 1 part by weight of sugar, and compositions for coating medicinal pill and tablet cores comprising an aqueous solution of gelatin and sugar containing 1.5 to 4.5 parts by weight of gelatin to 1 part by weight of sugar.

The invention also provides a process for pan-coating medicinal pill and tablet cores containing a medicament which comprises applying to untreated cores or to cores pretreated with a sub-coating and sizing material, while the cores are rotating in a coating pan, an amount of an aqueous solution of gelatin and sugar containing 1.5 to 4.5 parts by weight of gelatin to 1 part by weight of sugar just sufficient to produce a thin film of the solution over the cores, then, at the moment the coated cores begin to adhere to one another, applying sufficient talc to allow the coated cores to roll free, drying the coating with cold air and repeating these steps in sequence until a coating of desired thickness is obtained. By the technique of this invention the coating can be applied in an apparatus of the type con-

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ventionally used in pan-coating medicinal pill and tablet cores.

Owing to the use of gelatin, the coatings of the pills and tablets in accordance with the present invention have high structural strength and elasticity but nevertheless are known to be suitable for ingestion by humans and will dissolve readily in the secretions of the stomach and intestines when brought into contact with them. The coating provided by this invention additionally protects the tablet core containing the medicament from moisture, oxygen and other substances that may cause variation in the medicinal value of the active ingredient or ingredients, moreover, it provides all the desirable characteristics of hardness combined with sufficient elasticity to produce a coating highly resistant to chipping and breaking. The gelatin coating of this invention sets to a hard, elastic film which shows no tendency to become tacky at temperatures of about 100°—120°F. and a relative humidity (RH) as high as 60—100% such as would be encountered in tropical or subtropical countries where pills and tablets may be stocked.

In a practical method of carrying out this invention, the composition for coating the medicinal pill and tablet cores is prepared in conventional manner. If a coloured coating is desired, a dye is dissolved in this gelatin syrup. An advantageous gelatin syrup for use in coating the medicinal cores contains from about 25 to 40%, preferably 33%, total solids on a weight-to-weight basis in the aqueous solution. The tablet or pill cores are coated by applying a multiplicity of thin superimposed layers of this syrup to the core itself or to cores pretreated with a sub-coating and/or sizing or other material inert to the medicament contained in the core and to the gelatin coating to be applied to it. If a sizing is applied to the core it is preferred to superimpose on it a binding material such as a film of a gelatin-acacia solution, or other mucilaginous substance as agar, tragacanth, methylcellulose, carboxy-methylcellulose, zein or other known substances useful for this purpose. The application of the binding material ensures a firm bond with the gelatin syrup charges to be applied thus avoiding any possibility of pulling as the gelatin coating is built up.

The gelatin syrup may be prepared by dissolving the gelatin and sugar in hot or cold water, either by dissolving each separately and then subsequently mixing the two solutions, or by first dissolving the gelatin or sugar and subsequently the other ingredient in the same aqueous medium, or by intimately mixing the gelatin and sugar and then slowly adding the mixture with constant stirring to water heated in a steam-jacketed kettle and continuing the stirring and heating until all of the gelatin and sugar has dissolved, or by soaking the gelatin in cold water overnight and then dissolving the sugar in the gelatin solution by heating and stirring. The important consideration in preparing gelatin syrup is to maintain the ratio of gelatin to sugar within the ratio of 1.5 to 4.5 parts by weight of gelatin to 1 part by weight of sugar to ensure that the gelatin syrup can be applied in multiple layers by the pan coating process and upon drying will have the desirable characteristics described above for it.

Either of the two fundamental types of gelatin, Type A or Type B, can be employed in preparing the gelatin syrup, and jelly strengths ranging from 90 to 300 Bloom have been used successfully in preparing the syrup, although it is preferred to use jelly strengths ranging between 200 and 250 Bloom, most suitable 225 Bloom. Type A gelatin is made from acid-conditioned collagen and Type B from lime-conditioned collagen. For the most part, gelatin from acid-conditioned stock (Type A) is made from frozen porkskins, and limed gelatin (Type B) from calfskins, beefhides and also from demineralized cattle bones (ossein). Although there are some differences in characteristics of Type B gelatins, depending on whether they are manufactured from calfskins, beefhides or ossein, these differences are slight and since for use as a protective colloid it is usually possible to substitute one for another, manufacturers generally do not differentiate one from another when the gelatin is prepared and sold. The jelly strength of gelatin is determined by making up a gelatin gel under standard conditions (6.67% concentration chilled for 17 hours at 10° C.) and testing by means of the Bloom gelometer, which is a type of penetrometer. The Bloom value is the number of grams required to force a half-inch plummet 4 millimetres into the jelly. The Bloom value is roughly proportional to the molecular weight and also the viscosity. An especially satisfactory gelatin syrup for use in pan coating tablet and pill cores according to this invention can be made from 100% porkskins (Type A gelatin) having a jelly strength of approximately 225 Bloom.

The medicinal cores are coated by placing the untreated or pretreated cores in a pan coating apparatus and applying warm gelatin syrup at about 70°C, (58°F.), while rotating the cores in the pan at a room temperature of about 76°F. and a relative humidity (RH) of about 37%. As stated above, the cores can be used in their untreated form or, if necessary or desired, the cores can be pretreated in any of the usual ways such as applying a subcoating of a heavy syrup, i.e. sugar solution and the like, or by applying a sizing coating such as a gelatin-acacia solution, shellac or other known sizing coatings or a combination of subcoating and sizing coating if this is considered desirable or necessary for any particular type core which is to be coated subsequently with gelatin. It is important that only enough gelatin syrup is poured over the rotating cores to coat all of the cores with a thin film. If too much solu-

tion is used, it is more difficult to dry the film and overcome the tackiness of the coating thus greatly increasing the possibility of spoiling the coating. Ordinarily, about 5 fluid ounces per charge of about 70,000 cores weighing about 60 pounds is a suitable amount of gelatin syrup when applied at about 70°C. This quantity of gelatin syrup can be slightly increased or decreased depending upon prevailing temperature and humidity conditions.

After applying the gelatin solution, rotation of the pan is continued and the condition of the tablets is closely observed. Initially all of the coated cores roll freely, but as the water evaporates the coating becomes more viscous and the cores begin to coalesce. At the moment the tablets become tacky, which is indicated by their tendency to adhere to one another, i.e. coalesce, a small amount of talc, just enough to overcome the tackiness of the coating, is dusted through gauze onto the coated cores. The gauze is advantageously of medium grade porosity or of fine porosity as this ensures precision in dusting which is important in pan-coating tablet cores with a gelatin syrup. Too little talc will not overcome the tendency of the coated cores to adhere to one another and if they are permitted to coalesce, the coating is spoiled. On the other hand, too much talc will roughen the surface of the coating and also cause spotting. The amount of talc dusted on the coated cores must be adjusted by observation, and, as stated above, must be just sufficient to overcome the tackiness of the coating and prevent the cores from sticking one to another. The U.S.P. grade talc generally is used to dust the coating but any other talc of substantially the same purity and fineness could be substituted in this step. If the gelatin syrup used in pan-coating the tablet and pill cores is coloured, the same dye is added to the talc, as this too will overcome spotting as the coating is built up.

As soon after dusting with talc as the coated cores roll free, cold air is blown over the rotating coated cores until they become thoroughly dry. For a load of approximately 70,000 cores weighing 60 pounds, the drying time is approximately 25 minutes. The drying time will, of course, vary with the number of cores in each load and also with the amount of gelatin syrup applied and with the relative humidity. It is important that cold air be used in the drying to effect hardening of the gelatin syrup on the cores as warm air will soften the gelatin and prevent proper hardening of the film. Air, cooled to about 60 to 65°F. has been used satisfactorily in the drying step.

It is also desirable that the relative humidity of the room where the pan-coating is being done be maintained below about 40% and preferably between 30—38% RH and that the temperature preferably be maintained between about 75—80°F. Above this relative humidity, the moisture in the air tends to make the gelatin too soft and retards the rate of drying. The more moisture in the air, the softer the gelatin and the greater chance that some of the moisture will seep into the core material, thus causing deleterious effects such as inactivation of the active ingredient and the like. In general, the lower the humidity the quicker the coating will dry to a hard, durable film.

The above-described coating, dusting and drying steps are known in the art as a charge. This charge is repeated any number of times to produce a coated tablet of any desired size. As few as 10 charges provides a coating which will pass the hardness and stability tests for most tablets. If, of course, it is desired to prepare a coating which will not break or readily dissolve if held in the mouth or chewed, then 25 or more charges can be applied to the cores. Hexylresorcinol containing cores which received 10 charges of the gelatin syrup of this invention were found to satisfactorily pass the hardness test defined for them by the United States Pharmacopeia and were found to disintegrate in less than 4 hours as is required for tablets or pills containing hexyl resorcinol.

If the coating in the core is to be coloured, then the dye must be added to the gelatin solution as well as to the talc and in each instance the dye can be added by known methods.

As a rule, it is not necessary to polish the gelatin coatings of this invention, as a smooth, lustrous surface generally results from the pan-coating of this composition. However, the coated pills and tablets can be run in a polishing machine if it is desired to enhance the lustre, but no talc or wax should be used if this is done.

The following examples, in which the gallons referred to are U.S. gallons, illustrate the method by which tablet and pill cores are pan-coated with a gelatin syrup as well as a suitable gelatin syrup for use in this procedure. It is to be understood, of course, that modifications can be made in the technique and in the materials to adjust each of them to the particular condition of temperature, humidity, and quantity of cores to be coated, all of which modifications are within the skill of those working in this art.

EXAMPLE I

Gelatin pan-coating of cores each containing 0.15 grams hexylresorcinol

(a) *Gelatin Syrup*

Sugar U.S.P. medium granular	1 lb.
Gelatin U.S.P. (Type A, 225 Bloom)	1 lb. 8 oz.
Erythrosine, certified, No. 773, Red, F.D. & C. No. 3	1 oz.
Water, distilled	1 gal.

The sugar, gelatin and dye were placed in a stainless steel container and intimately mixed by stirring. The water was added slowly with continued stirring and then the mixture was heated in a water bath maintained at a temperature between about 85—95°C. with stirring until a clear solution was obtained. This solution was strained through a double thickness of gauze having a 28—24 mesh to remove any undissolved particles.

(b) *Dusting Powder*

Talc U.S.P.	100 lbs.
Erythrosine certified No. 773 Red F.D. & C. No. 3	1 lb.
Water, distilled q.s.	(Approx. 2 gal., 2 pints)

The dye was dissolved in 2 gallons of the distilled water by stirring and the solution then put through smooth surface qualitative type filter paper such as that sold by Arthur H. Thomas Company as filter paper No. 5268. The talc was placed in the pony mixer and while the mixer was running, the dye solution was added slowly thereto. While still running, the additional 2 pints of distilled water were added and mixing continued for about 20 to 30 minutes. The dyed talc was then granulated by passing through a comminuting machine equipped with a No. 4 screen and impacters and run at medium speed after which it was returned to the pony mixer and remixed for about five minutes. The granules then were spread out about half an inch thick on drying trays and dried for about 12 hours at 130 to 150°F. When the granulation was completely dry, it was again passed through a comminuting machine equipped with a No. 00 screen and impacters and run at high speed. The comminuting was repeated a second time and the dyed talc then was ready for use as dusting powder in the following procedure:

(c) *Pan Coating*

60 lbs. (71,186 tablets, 10 weighing 59 grs.) of the hexyl-resorcinol-containing cores having 2 charges of a gelatin-acacia solution, were placed in a coating pan and the pan started in motion. The room conditions were regulated to about 76°F. and the RH to about 37% and about 5 fluid ounces of the gelatin solution, previously heated to 70°C., was poured over the sized cores. The pan was maintained in rotation and as soon as the cores showed a tendency to adhere one to another about 2 ounces of the red talc was dusted on the cores through a double thickness of medium gauge gauze having a 28 x 24 mesh. The coated cores were observed to roll freely and cold air, maintained at about 17°C., then was blown over the rotating cores for from 20 to 25 minutes or until the coating material was thoroughly dry. The charge was repeated 49 times, thus applying 50 charges to the sized hexylresorcinol cores. The coated tablets then were transferred to a polishing pan which was set in motion and allowed to run for approximately 30 minutes to produce a higher lustre. It is to be observed that no dusting or wax is needed to produce a high lustre on gelatin coating such as applied to these cores.

Samples of the coated tablets were taken when 10 charges had been applied and also when 25, 43 and 50 charges had been applied to the cores. These samples were tested and found to have the following characteristics:—

No. of Charges	Hardness[1]	Disintegration[2] Time	Moisture[3]	Av. wgt. of 10 Pills (grains ± 3%)
10	O.K.	under 4 hours	0.62—0.8%	63
25	O.K.	under 4 hours	0.62—0.70%	67
43	O.K.	under 4 hours	0.70%	72
50	O.K.	under 4 hours	0.72—0.90%	75

[1] Figures represent 10 readings on Strong Cobb Hardness-Tester Apparatus and represents withstanding at least 15 pounds per total pressure exerted upon tablet.

[2] Disintegration Time determined by method outlined in U.S. Pharmacopeia Vol. XV, pp. 936—38, using simulated gastric fluid.

[3] Moisture content represents average percent loss in weight of 20 crushed tablets after drying 4 hours in a vacuum oven maintained at 60° C.

Example II

Gelatin pan coating of cores each containing 1 mg. Fluorocortisone Acetate

(a) *Gelatin Syrup*

Sugar USP medium granular	1 lb.
Gelatin USP (Type B, 225 Bloom)	1 lb. 8 oz.
Erythrosine, certified, No. 773 Red F.D. & C. No. 3	1 oz.
Water, distilled	1 gal.

The water was placed in a steam jacketed kettle and the gelatin, sugar and dye which had previously been intimately mixed, were added to it slowly with constant stirring. The steam was then turned on and the contents of the kettle were heated with continued stirring until all of the gelatin and sugar had dissolved and a clear solution was obtained. This solution then was strained through a double thickness of gauze having a 28 × 24 mesh.

(b) *Dusting Powder* Prepared as described in Example 1(b).

(C) *Pan Coating.*

60 lbs. of untreated fluorocortisone-acetate-containing cores were placed in a coating pan and coated with Type B gelatin syrup, prepared as described in step (a) above, in the same manner described in Example I (c). Twenty-five charges were applied and samples of the finished product were found to withstand at least 15 pounds pressure when tested on the Strong Cobb Hardness Tester apparatus, they disintegrate in less than 4 hours and had a moisture content of less than 1%.

EXAMPLE III

Gelatin pan coating of cores each containing 50,000 units Vitamin A Palmitate USP

(a) *Gelatin Syrup*

Sugar USP medium granular	1 lb.
Gelatin USP (Type A, 90 Bloom)	4 lb. 8 oz.
Tartrazine F.D. & C. Yellow No. 5	1 oz.
Water, distilled	1 gal.

The gelatin was added to the distilled water and allowed to stand overnight at room temperature. The next day, the sugar was added slowly with stirring and the dye dissolved in a small quantity of water then was added with stirring. The mixture was heated with constant stirring until a clear solution was obtained. The solution then was strained through a double thickness of gauze having a 28 × 24 mesh.

(b) *Dusting Powder*

The dusting powder was prepared in substantially the same manner as described in Example I (b) with the exception an equal quantity of tartrazine F.D. & C. Yellow No. 5 was employed instead of Red F.D. & C. No. 3

(c) *Pan-Coating*

60 lbs. of untreated cores each containing 50,000 units vitamin A palmitate were placed in a coating pan and coated with the Type A, 90 Bloom gelatin syrup, prepared as described in step (a), in the same manner described in Example I, (c). 50 charges were applied to the cores and samples of the finished coated tablets satisfactorily passed the hardness, disintegration and moisture tests in that they resisted a pressure of at least 15 pounds when tested on the Strong Cobb Hardness Tester Apparatus, disintegrated in less than 4 hours and had a moisture content of less than 1%.

EXAMPLE IV

Gelatin pan-coating of cores each containing 0.3 gms. of a 1:3 mixture of hexylresorcinol and piperazine

(a) *Gelatin Syrup*

Sugar USP medium granular	1 lb.
Gelatin USP (Type A, 250 Bloom)	1 lb. 8 oz.
Guinea Green B. F. D. & C. Green No. 1)	1 oz.
Water, distilled	1 gal.

The gelatin syrup was prepared by substantially the same method described in Example I (a) but using the above ingredients.

(b) *Dusting Powder*

The dusting powder was prepared in substantially the same way as described in Example I (b) with the exception that an equal quantity of Guinea Green B, F.D. & C. Green No. 1 was substituted for the Red F.D. & C No. 3.

(c) *Pan-Coating*

60 lbs. of the hexylresorcinol-piperazine-containing cores, previously sized with shellac and having a binding coating comprising two charges of a gelatin-acacia solution, were placed in a coating pan and coated with a Type A, 250 Bloom gelatin syrup prepared as described above. 15 Charges were applied to the cores by substantially the same procedure described in Example I (c) and samples of the finished coated tablets satisfactorily passed the hardness, disintegration and moisture tests in that they withstood at least 15 pounds pressure on the Strong Cobb Tester Apparatus, they disintegrated in less than 4 hours and had a moisture content of less than 1%.

EXAMPLE V

Gelatin pan-coating of cores each containing 0.1 gms. hexylresorcinol

	Sugar USP medium granular	1 lb.
(a)	Gelatin USP (Type A, 225 Bloom)	4 lb. 8 oz.
	Erythrosine certified, No. 773 Red F.D. & C. No. 3	1 oz.
	Water, distilled	1 gal.

The gelatin syrup was prepared in the same manner described in Example I (a) but using the above ingredients.

(b) *Dusting Powder*. Prepared as described in Example I (b).

(c) *Pan-Coating*

60 lbs. of the hexylresorcinol-containing cores having two charges of a gelatin-acacia solution were placed in a coating pan and coated with the Type A, 225 Bloom gelatin syrup prepared as described in substantially the same manner as described in Example I (c). 15 charges were applied to the cores and samples of the coated tablets satisfactorily passed the hardness, disintegration and moisture tests in that they withstood a pressure of at least 15 pounds on the Strong Cobb Hardness Tester Apparatus, they disintegrated in less than 4 hours and had a moisture content of less than 1%.

While the invention has been described with reference to certain particular cores it is to be understood that any untreated or treated cores can be employed in the process of this invention and the gelatin syrup of this invention can be applied thereto to form a hard, tenacious, pharmaceutically elegant coating thereon.

Similarly any suitable dusting powder can be applied and the talc USP employed in preparing the dusting powders in the examples contained herein can be replaced by any other suitable talc having substantially the same fineness and purity as talc USP and the colouring material can be replaced by any colouring material approved for use in food, drugs and cosmetics (F.D. & C.) or in drugs and cosmetics (D. & C.).

Slight modifications can be made in the temperature and relative humidity conditions under which the cores are pan-coated with the gelatin syrup of this invention provided the temperature and relative humidity conditions do not prevent hardening of the charges as they are applied to the cores.

WHAT WE CLAIM IS:—

1. A medicinal tablet or pill including a core comprising a medicament and an exterior coating comprising a multiplicity of thin, superimposed layers of intermixed gelatin and sugar in the proportion of 1.5 to 4.5 parts by weight of gelatin to 1 part by weight of sugar.

2. A composition for coating medicinal pill and tablet cores comprising an aqueous solution of gelatin and sugar containing 1.5 to 4.5 parts by weight of gelatin to 1 part by weight of sugar.

3. A composition according to Claim 2, in which the aqueous solution contains from 25% to 40% total solids.

4. A composition according to Claim 3, in which the aqueous solution contains 33% total solids.

5. A process for pan-coating medicinal pill and tablet cores containing a medicament which comprises applying to untreated cores or to cores pretreated with a sub-coating and sizing material, while the cores are rotating in a coating pan, an amount of solution as claimed in any one of Claims 2—4 just sufficient to produce a thin film of the solution over the cores, then, at the moment the coated cores begin to adhere to one another, applying sufficient talc to allow the coated cores to roll free, drying the coating with cold air, and repeating these steps in sequence until a coating of desired thickness is obtained.

6. A process as claimed in Claim 5, in which the syrup is at a temperature of about 158°F, the room temperature is about 76°F, and the relative humidity is about 37%.

7. A process as claimed in Claim 5, in which the relative humidity is 30—38%.

8. A process as claimed in Claim 5 or 7, in which the room temperature is 75—80°F.

9. A process as claimed in Claim 5, substantially as hereinbefore described.

10. A process for preparing pan-coated tablets and pills, substantially as hereinbefore described with reference to the foregoing Examples.

11. A pan-coated tablet or pill, when the coating has been applied by a process as claimed in any one of Claims 5—10.

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Leamington Spa: Printed for Her Majesty's Stationery Office, by the Courier Press.—1960.
Published by The Patent Office, 25, Southampton Buildings, London, W.C.2, from which copies may be obtained.